Complete Summary

GUIDELINE TITLE

Pharmacologic management of acute attacks of migraine and prevention of migraine headache.

BIBLIOGRAPHIC SOURCE(S)

Snow V, Weiss K, Wall EM, Mottur-Pilson C. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. Ann Intern Med 2002 Nov 19;137(10):840-52. [121 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Migraine headache

GUIDELINE CATEGORY

Diagnosis Management Prevention Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine

INTENDED USERS

Physicians

GUI DELI NE OBJECTI VE(S)

To provide recommendations for the management of acute attacks of migraine and prevention of migraine headaches

TARGET POPULATION

- Patients with acute migraine attacks, with or without aura
- Patients with migraine who are candidates for preventive drug therapy

INTERVENTIONS AND PRACTICES CONSIDERED

Treatment

- 1. Nonsteroidal anti-inflammatory drugs
 - Aspirin
 - Ibuprofen
 - Naproxen sodium*
 - Tolfenamic acid
 - Acetaminophen plus aspirin plus caffeine
- 2. Migraine-specific agents (triptans, dihydroergotamine [DHE])
 - Oral naratriptan
 - Rizatriptan
 - Zolmitriptan
 - Oral and subcutaneous sumatriptan
 - DHE nasal spray
- 3. Antiemetics (e.g., metoclopramide) for migraines with nausea and/or vomiting

Considered but not recommended as first-line treatment: opioids (e.g., butorphanol nasal spray)

Prevention

- 1. Propranolol
- 2. Timolol
- 3. Amitriptyline
- 4. Divalproex sodium
- 5. Sodium valproate
- 6. Additional therapies include flunarizine, lisuride, pizotifen, time-released DHE, and methysergide
- 7. Education of patients in self-management

^{*}Note from the National Guideline Clearinghouse (NGC): On December 23, 2004, the FDA issued a public health advisory concerning the use of non-steroidal anti-inflammatory drug products (NSAIDs) including the COX-2 selective agents Celebrex (celecoxib), Bextra (valdecoxib), and a non-selective NSAID, naproxen (sold as Aleve, Naprosyn, and other trade name and generic products). See the FDA Web site for more information.

MAJOR OUTCOMES CONSIDERED

- Relief of migraine headache pain
- Prevention of migraine headaches
- Adverse effects of migraine medications

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

These guidelines are based on two previously published papers: "Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks," by Matchar and colleagues, and "Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management for Prevention of Migraine," by Ramadan and coworkers. See the Companion Documents field for complete references to these works.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The methods used to analyze the evidence are detailed in two previously published papers used as the basis for this guideline: "Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management of Acute Attacks," by Matchar and colleagues, and "Evidence-Based Guidelines for Migraine Headache in the Primary Care Setting: Pharmacological Management for Prevention of Migraine," by Ramadan and coworkers. See the Companion Documents field for complete references to these works.

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were approved by the American College of Physicians (ACP) Board of Regents on 26 March 2001, and by the American Academy of Family Physicians Board of Directors on 8 August 2001.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: Throughout the text of these recommendations, asterisks indicate drugs that are currently not available in the United States.

Recommendation 1: For most migraine sufferers, nonsteroidal antiinflammatory drugs (NSAIDs) are first-line therapy.

To date, the most consistent evidence exists for aspirin, ibuprofen, naproxen sodium^{1,} tolfenamic acid*, and the combination agent acetaminophen plus aspirin plus caffeine. There is no evidence for the use of acetaminophen alone.

Recommendation 2: In patients whose migraine attack has not responded to nonsteroidal anti-inflammatory drugs, use migraine-specific agents (triptans, dihydroergotamine [DHE]).

There is good evidence for the following triptans: oral naratriptan, rizatriptan, and zolmitriptan; oral and subcutaneous sumatriptan; and DHE nasal spray. Few data in the literature demonstrate which triptans are more effective. Oral opiate combinations and butorphanol may be considered in acute migraine when sedation side effects are not a concern and the risk for abuse has been addressed.

Recommendation 3: Select a nonoral route of administration for patients whose migraines present early with nausea or vomiting as a significant component of the symptom complex. Treat nausea and vomiting with an antiemetic.

Evidence is limited, but in some patients, concomitant treatment with an antiemetic and an oral migraine medication may be appropriate. Antiemetics should not be restricted to patients who are vomiting or likely to vomit. Nausea itself is one of the most aversive and disabling symptoms of a migraine attack and should be treated appropriately.

Recommendation 4: Migraine sufferers should be evaluated for use of preventive therapy.

Generally accepted indications for migraine prevention include 1) two or more attacks per month that produce disability lasting 3 or more days per month; 2) contraindication to, or failure of, acute treatments; 3) use of abortive medication more than twice per week; or 4) the presence of uncommon migraine conditions, including hemiplegic migraine, migraine with prolonged aura, or migrainous infarction.

Recommendation 5: Recommended first-line agents for the prevention of migraine headache are propranolol (80 to 240 mg/d), timolol (20 to 30 mg/d), amitriptyline (30 to 150 mg/d), divalproex sodium (500 to 1500 mg/d), and sodium valproate (800 to 1500 mg/d).

Medications with proven efficacy but limited published data on adverse events or frequent or severe adverse events include flunarizine*, lisuride*, pizotifen*, time-released DHE*, and methysergide.

Recommendation 6: Educate migraine sufferers about the control of acute attacks and preventive therapy and engage them in the formulation of a management plan. Therapy should be reevaluated on a regular basis.

There is strong consensus about the need for educating people with migraine. The physician must help the patient establish realistic expectations by discussing therapeutic options and their benefits and harms, such as medication-overuse headache. Encouraging patients to be actively involved in their own management by tracking their own progress through daily flow sheets, for example, may be especially useful. Diaries should measure attack frequency, severity, and duration; resulting disability; response to type of treatment; and adverse effects of medication. Patient input can provide the best guide to treatment selection.

1Note from the National Guideline Clearinghouse (NGC): On December 23, 2004, the FDA issued a public health advisory concerning the use of non-steroidal anti-inflammatory drug products (NSAIDs) including the COX-2 selective agents Celebrex (celecoxib), Bextra (valdecoxib), and a non-selective NSAID, naproxen (sold as Aleve, Naprosyn, and other trade name and generic products). See the FDA Web site for more information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

This guideline is based on the following two previously published guidelines (see the Companion Documents field):

- Matchar DB, Young WB, Rosenberg JH, Pietrzak MP, Silberstein SD, Lipton RB, et al. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. 2000.
- Ramadan NM, Silberstein SD, Freitag FG, Gilbert TT, Frishberg BM. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. 2000.

The recommendations made in this guideline differ somewhat from those in the previously published guidelines because different thresholds of evidence were needed for making a positive recommendation. The American College of Physicians (ACP) historically has not used a grading system for guideline recommendations because its development process mandates the use of only high-quality evidence (that is, randomized, controlled trials of "A" level evidence) as a basis for recommendations.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Rapid and consistent treatment of acute migraine attacks may avoid headache recurrence, restore the patient's ability to function, and minimize the use of backup and rescue medications.

Subgroups Most Likely to Benefit:

Anticonvulsants may be especially useful in patients with prolonged or atypical migraine aura.

POTENTIAL HARMS

- Adverse effects of the triptans include chest symptoms, but postmarketing data indicate that true ischemic events are
 rare.
- · Studies have documented frequent adverse events of ergotamine or ergotamine-caffeine.
- Adverse effects reported most commonly with beta-blockers were fatigue, depression, nausea, dizziness, and insomnia.
 These symptoms appear to be fairly well tolerated and seldom caused premature withdrawal from trials.
- Drowsiness, weight gain, and anticholinergic symptoms were frequently reported with the tricyclic antidepressants studied, including amitriptyline.
- Adverse events with anticonvulsants are not uncommon and include weight gain, hair loss, tremor, and teratogenic
 potential, such as neural tube defects.
- The most commonly reported adverse events with all nonsteroidal anti-inflammatory drugs (NSAIDs) were gastrointestinal symptoms, including nausea, vomiting, gastritis, and blood in the stool.
- The most commonly reported events for all the ergot alkaloids were gastrointestinal symptoms.
- There are reports of retroperitoneal and retropleural fibrosis associated with long-term, mostly uninterrupted administration of methysergide. Other adverse events most commonly reported included gastrointestinal symptoms and leg symptoms (restlessness or pain).
- Published data on adverse events associated with lisuride are limited, and pizotifen is often associated with weight gain and drowsiness.
- Symptoms reported with nifedipine, nimodipine, cyclandelate, and verapamil agents included dizziness, edema, flushing, and constipation.
- Adverse events reported with flunarizine include sedation, weight gain, and abdominal pain. Depression and extrapyramidal symptoms can be observed, particularly in elderly persons.

CONTRAINDICATIONS

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Triptans are contraindicated in patients with risk for heart disease, basilar or hemiplegic migraine, or uncontrolled hypertension.

QUALIFYING STATEMENTS

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Clinical practice guidelines are "guides" only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians judgment. All American College of Physicians (ACP) clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

Staying Healthy

IOM DOMAIN

Effectiveness

Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Snow V, Weiss K, Wall EM, Mottur-Pilson C. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. Ann Intern Med 2002 Nov 19;137(10):840-52. [121 references] <u>PubMed</u>

ADAPTATION

This guideline is based on the following two previously published guidelines (see the Companion Documents field):

- Matchar DB, Young WB, Rosenberg JH, Pietrzak MP, Silberstein SD, Lipton RB, et al. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. 2000.
- Ramadan NM, Silberstein SD, Freitag FG, Gilbert TT, Frishberg BM. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. 2000.

DATE RELEASED

2002 Nov

GUIDELINE DEVELOPER(S)

American Academy of Family Physicians - Medical Specialty Society American College of Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

Financial support for American College of Physicians (ACP) guideline development comes exclusively from the American College of Physicians operating budget.

GUI DELI NE COMMITTEE

Clinical Efficacy Assessment Subcommittee (American College of Physicians [ACP]) and the Commission on Scientific Activities of the American Academy of Family Physicians (AAFP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Vincenza Snow, MD; Kevin Weiss, MD; Eric M. Wall, MD, MPH; Christel Mottur-Pilson, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American College of Physicians (ACP) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106-1572.

AVAILABILITY OF COMPANION DOCUMENTS

The following related guidelines are available:

- Matchar DB, Young WB, Rosenberg JH, Pietrzak MP, Silberstein SD, Lipton RB, et al. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management of acute attacks. 2000.
- Ramadan NM, Silberstein SD, Freitag FG, Gilbert TT, Frishberg BM. Evidence-based guidelines for migraine headache in the primary care setting: pharmacological management for prevention of migraine. 2000.

Electronic copies: Available from the American Academy of Neurology Web site.

The following evidence summaries are also available:

- Gray RN, McCrory DC, Eberlein K, Westman EC, Hasselblad V. Self-Administered Drug Treatments for Acute Migraine Headache. Technical Review, 2.4, February 1999. (Prepared for the Agency for Health Care Policy and Research under Contract No. 290-94-2025. Available from the National Technical Information Service; NTIS Accession No. 127854.)
- Gray RN, McCrory DC, Eberlein K, Westman EC, Hasselblad V. Parenteral Drug Treatments for Acute Migraine Headache.
 Technical Review, 2.5, February 1999. (Prepared for the Agency for Health Care Policy and Research under Contract No. 290-94-2025. Available from the National Technical Information Service; NTIS Accession No. 127862.)

Gray RN, Goslin RE, McCrory DC, Eberlein K, Tulsky J, Hasselblad V. Drug Treatments for the Prevention of Migraine.
 Technical Review 2.3, February 1999. (Prepared for the Agency for Health Care Policy and Research under Contract No. 290-94-2025. Available from the National Technical Information Service; NTIS Accession No. 127953.)

Electronic copies: Available from the <u>Duke Center for Clinical Health Policy Research Web site</u>.

PATIENT RESOURCES

The following is available:

 Summaries for patients. Guidelines for the treatment and prevention of migraine headaches. Ann Intern Med 2002 Nov 19;137(10):150. Available in <u>HTML</u> and <u>Portable Document Format (PDF)</u> from the American College of Physicians (ACP) Web site.

Print copies: Available from the American College of Physicians, 190 N. Independence Mall West, Philadelphia, PA 19106-1572

The following is also available:

• Tension, migraine, cluster? Which headache type do you suffer from? Patient Brochure. (Product #700100220)

Information on how to order this brochure is available at the <u>ACP Web site</u> or by ordering through ACP Customer Service: 800-523-1546, extension 2600 or 215-351-2600.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 6, 2003. The information was verified by the guideline developer on May 14, 2003. This summary was updated by ECRI on January 12, 2005 following the release of a public health advisory from the U.S. Food and Drug Administration regarding the use of some non-steroidal anti-inflammatory drug products.

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